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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Kenneth A. Jones, et al.
Serial No. : 09/211,755 Group Art Unit: 1646
Filed : December 15, 1998 Examiner: M. Brannock
For : DNA Encoding a GABA_BR2 Polypeptide and Uses
Thereof

1185 Avenue of the Americas
New York, New York 10036
April 20, 2000

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

COMMUNICATION IN RESPONSE TO MARCH 20, 2000 OFFICE ACTION AND
FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

This Communication is submitted in response to the Office Action issued March 20, 2000 by the U.S. Patent and Trademark Office in connection with the above-identified application. A response to the March 20, 2000 Office Action is due April 20, 2000. Accordingly, this Amendment is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

In the March 20, 2000 Office Action, the Examiner to whom the subject application is assigned, required restriction under 35 U.S.C. §121 to one of the following allegedly independent and distinct inventions:

- I. Claims 190-207, 246 and 249, drawn to a method for identifying ligands of a GABA_BR1/R2 receptor and a process of preparing a pharmaceutical composition;

Kenneth A. Jones, et al.
Serial No.: 09/211,755
Filed: December 15, 1998
Page 2



- II. Claims 208, 210, 213, 214, 221-225, 228-231, 233 and 234-240, drawn to a method for identifying agonists of a GABA_BR1/R2 receptor;
- III. Claims 209, 210, 215-223, 226-230, and 232-240, drawn to a method for identifying antagonists of a GABA_BR1/R2 receptor;
- IV. Claims 211 and 241, 247 and 249, drawn to a composition comprising an agonist and a process of preparing a pharmaceutical composition;
- V. Claims 212 and 241, 248 and 249, drawn to a composition comprising an antagonist and a process of preparing a pharmaceutical composition;
- VI. Claims 242 and 245, drawn to a process for identifying and synthesizing a compound;
- VII. Claims 243 and 245, drawn to a process for identifying and synthesizing an agonist; and
- VIII. Claims 244 and 245, drawn to a process for identifying and synthesizing an antagonist.

The Examiner noted that the claims that appear in more than one group will be searched only as they relate to the elected Group. For example, if Group IV is elected, then claim 241 would only be examined to the extent it reads on an agonist, and if Group V is elected, then claim 241 would only be examined to the extent that it reads on an antagonist.

The Examiner alleged that the inventions are distinct, each from the other. The Examiner alleged that Groups II and III are

related to Groups IV and V, respectively, as process of making and product made. The Examiner concluded that in the instant case, the agonist of Group IV and the antagonist of Group V are products that could potentially be acquired through sources unrelated to the methods of either Group II or Group III, e.g. the compounds could be obtained through commercial sources if these compounds were known in the art. The Examiner further alleged that Groups VII and VIII are related to Groups IV and V, respectively, as process of making and product made. The Examiner concluded that the agonist of Group IV and the antagonist of Group V are products that could be acquired through sources unrelated to the methods of either Group VII or Group VIII, e.g., the compounds could be obtained through commercial sources if these compounds were known in the art. The Examiner alleged that the agonist of Group IV is patentably distinct from the methods of Groups I, III, VI, and VIII, and the antagonist of Group V is patentably distinct from the methods of Groups I, II, VI, and VII, because one is not required of the other.

The Examiner alleged that Groups IV and V are directed to products that are distinct, both physically and functionally, and are not required for the other, and are therefore patentably distinct. The Examiner alleged that the agonist of Group IV and the antagonist of Group V would be expected to have different chemical structures, and, by definition, to have opposite or divergent effects in a biological system. The Examiner further alleged that Groups I and VI, which require an assay of binding, are directed to methods that are distinct both physically and functionally from the methods of Groups II, III, VII, and VIII, which require an assay of function, and are not required one for the other.

The Examiner alleged that methods of Groups I, II, and III are distinct from the methods of Groups VI, VII, and VIII because the methods of Groups VI, VII, and VIII require the additional step of synthesis which is not required of Groups I, II, and III. The Examiner further alleged that the methods of Groups VI, VII, and VIII are each patentably distinct, one from the other, because each requires the chemical synthesis of structurally distinct compounds. The Examiner concluded that the methods of Group II for identifying an agonist and the methods of Group III for identifying an antagonist are patentably distinct because the goal of each is to identify structurally distinct compounds with opposite and divergent biological functions.

The Examiner concluded that a search and examination of all the groups in one patent application would result in undue burden, since the searches for the eight groups are not co-extensive, the classification is different, and/or the subject matter is divergent.

The Examiner stated that for a reply to this requirement to be complete, applicants' response must include an election of the invention to be examined even though the requirement be traversed. The Examiner additionally stated that upon cancellation of claims to a non-elected invention, the inventorship must be amended if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application.

In response to this restriction requirement, applicants' undersigned attorney hereby elects, with traverse, to prosecute the invention of Examiner's Group II, i.e. claims 208, 210, 213, 214, 221-225, 228-231, 233, and 234-240, drawn to a method for identifying agonists of a GABA_BR1/R2 receptor.

Kenneth A. Jones, et al.
Serial No.: 09/211,755
Filed: December 15, 1998
Page 5

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction of Examiner's Group II from Examiner's Groups I and III-VIII be withdrawn in view of the fact that the claims of Examiner's Group II are not independent of Examiner's Groups I and III-VIII. Applicants further maintain that the claims of Examiner's Group II and Examiner's Groups I and III-VIII do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group II are related to the claims of Examiner's Groups I and III-VIII in that the claims in all of the groups are related to the GABA_BR1/R2 receptor.

Applicants therefore respectfully assert that two independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Kenneth A. Jones, et al.
Serial No.: 09/211,755
Filed: December 15, 1998
Page 6

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to a GABA_BR1/R2 receptor will reveal whether any prior art exists as to methods for identifying ligands of a GABA_BR1/R2 receptor, agonists of a GABA_BR1/R2 receptor, and antagonists of a GABA_BR1/R2 receptor (Groups I, II, and III, respectively), compositions comprising an agonist or an antagonist (Groups IV and V, respectively), and processes for identifying and synthesizing a compound, an agonist, or an antagonist (Groups VI, VII, and VIII, respectively). Since there is no burden on the Examiner to examine Groups I-VIII in the subject application, the Examiner must examine the entire application on the merits.

Applicants maintain that claims 190-249 define a single inventive concept. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 190-249 on the merits.

Fourth Supplemental Information Disclosure Statement

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following reference which is listed on the attached Form PTO-1449 (**Exhibit 1**) and attached hereto as **Exhibit 2**:

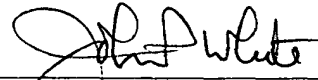
1. WO 00/14222, published March 16, 2000 (**Exhibit 2**).

Kenneth A. Jones, et al.
Serial No.: 09/211,755
Filed: December 15, 1998
Page 7

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided.

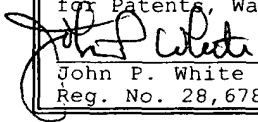
No fee is deemed necessary in connection with the filing of this Communication in Response to March 20, 2000 Office Action and Supplemental Information Disclosure Statement. However, if any such fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



John P. White
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4/20/00
Date